FEB 11 2005

K043006

TAB 10

510(K) SUMMARY

Official Contact

Zita Yurko
Manager, Regulatory Affairs
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

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Proprietary Name Millennium M10 Oxygen Concentrator

Common/Usual Name Millennium M10

Classification Name Generator, Oxygen, Portable (CAW).

Predicate Devices Respironics Millennium (K0972614)

SeQual Integra (K042262)

Device Description

The Millennium M10 Oxygen Concentrator is a medical device that produces concentrated oxygen from room air for delivery to a patient requiring oxygen therapy. It uses molecular sieve and a pressure swing adsorption process to concentrate oxygen from air. The device is capable of providing oxygen flow up to 10 LPM and is offered with an optional Oxygen Percentage Indicator.

Indications for Use

The Millennium M10 Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life support nor life sustaining.

Technological characteristics, comparison to predicate devices

The Respironics Millennium M10 has the same operating principles and same technology as the predicate devices. The Millennium M10 is capable of providing oxygen flow up to 10 LPM.

Performance testing

Performance, environmental, electrical, mechanical and electromagnetic compatibility testing was performed to prove the safety and effectiveness of the Millennium M10.

Conclusion

It is the conclusion of Respironics that the Millennium M10 is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Respironics, Incorporated
C/O Ms. Zita A. Yurko
Manager, Regulatory Affairs
Homecare Division
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550

Re: K043006
Trade/Device Name: Millennium M10 Oxygen Concentrator
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: December 22, 2004
Received: December 27, 2004

Dear Ms. Yurko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___Millennium M10 Oxygen Concentrator_____

Indications for Use:

The Millennium M10 Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life support nor life sustaining

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number K143006